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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,777	10/07/2003	Robert R. Gonnelli	BVTP-P01-034	6708

28120 7590 04/19/2007
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EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/681,777

Applicant(s)

GONNELLI ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,10,11,14,15 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,10,11,14,15 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10-11, 14, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Eicher et al. (6,132,755). Eicher discloses a delivery device for introducing a substance into or below the stratum corneum comprising a microneedle (23) having a distal end and an interior channel (28) that extends to the distal end, a removable plug (27) at the distal end of the channel to prevent tissue from entering the channel, a reservoir (24) capable of storing a fluid substance to be introduced into the biological tissue, and an adhesive patch (bottom of device) capable of adhering to biological tissue, wherein the plug comprises a bioerodible material (column 3, lines 30-40), wherein the plug comprises a barb and is cone-shaped, wherein the device comprises an array of microneedles, further comprising a flange (at top of device) that could be coupled to an external device, wherein the plug has a frangible seam (where

Art Unit: 3763

27 meets 23), and wherein the plug is secured to the exterior surface of the microneedle.

Claims 1, 5-7, 10-11, 14-15, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (US 2002/0082543). Park discloses a delivery device for introducing a substance into or below the stratum corneum comprising a microneedle (42) having a distal end and an interior channel that extends to the distal end, a removable plug (see page 7, 0089,0090) at the distal end of the channel to prevent tissue from entering the channel, a reservoir capable of storing a fluid substance to be introduced into the biological tissue, and an adhesive patch (bottom of device) capable of adhering to biological tissue, wherein the plug comprises a bioerodible material (page 7), wherein the plug comprises a barb and is cone-shaped, wherein the device comprises an array of microneedles, further comprising a flange (at top of device) that could be coupled to an external device, wherein the plug has a frangible seam, wherein the plug is secured to the exterior surface of the microneedle, and further comprising pumps for delivering fluid or drawing a sample.

Claims 1, 5-7, 10-11, 14-15, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gonnelli (US 2003/0135201). Gonnelli discloses a delivery device for introducing a substance into or below the stratum corneum comprising a microneedle (310) having a distal end and an interior channel that extends to the distal end, a removable plug (130) at the distal end of the channel to prevent tissue from entering the channel, a reservoir capable of storing a fluid substance to be introduced into the biological tissue, and an adhesive patch (bottom of device) capable of adhering

Art Unit: 3763

to biological tissue, wherein the plug comprises a bioerodible material, wherein the plug comprises a barb and is cone-shaped, wherein the device comprises an array of microneedles, further comprising a flange (at top of device) that could be coupled to an external device, wherein the plug has a frangible seam, wherein the plug is secured to the exterior surface of the microneedle, and further comprising pumps for delivering fluid or drawing a sample.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Arguments

Applicant's arguments with respect to claims 1, 5-7, 10-11, 14-15, and 21-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

Art Unit: 3763

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Theodore J. Stigell


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